

Operations Memo No. 15



VA COOPERATIVE STUDIES PROGRAM # 424

Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

Date: November 22, 1999

From: Drs William Boden and Robert O'Rourke

Subj: Importance of Enrolling Patients with Significant CAD

To: Study PIs, Co-PIs and coordinators

Thru: Trial Leadership

To date, there have been four (4) patients randomized to the COURAGE Trial who had no significant CAD (i.e., no lesion $\geq 50\%$ diameter stenosis by QCA). Obviously, including such patients in the COURAGE Trial represents a major recruitment violation.

We are attaching again, for your review, the angiographic criteria of what constitutes a "COURAGE-eligible" vessel.

It is imperative that we include **ONLY** those patients with significant proximal CAD or large vessels that subtend a major amount of myocardium.

We do not want low-risk patients enrolled as part of the COURAGE Trial; the inclusion of patients with low-risk coronary anatomy (i.e., patients with mid-distal LCX or OM disease) will adversely affect our trial hypothesis that PCI & medical therapy is superior to medical therapy alone. In short, we need to enroll patients with significant proximal CAD (single or multi-vessel) who are likely to benefit clinically from PCI.

We thank you for your attention and cooperation.

Angiographic Inclusion Criteria

Patients will be included in this study if percutaneous revascularization of all of the intended lesions is associated with a high (>90%) probability of success and low (<5%) probability of abrupt vessel closure. Specific inclusions:

- a) the stenosis represents $\geq 50\%$ diameter reduction,
- b) there is at least one vessel planned for angioplasty meeting one of the following criteria:
 - i) RCA: Proximal to the PDA in a right dominant vessel
 - ii) LCX: Proximal to 2 or more OM branches or proximal to the PDA + PL branches in a left dominant vessel
 - iii) LAD: Proximal or mid-vessel
 - iv) SVG or IMA: Graft must supply same region(s) as outlined above

Or

- v) In the opinion of the interventionalist, the coronary stenosis subtends a “major” mass of myocardium

Angiographic Exclusion Criteria:

Patients will be excluded from the study if the coronary anatomy suggests that the revascularization procedure would be excessively high risk or would not likely be successful. Specific exclusions include: excessive tortuosity of vessels proximal to a lesion, excessive angulation within a lesion, excessive lesion length, total chronic occlusion, inability to dilate because of excessive calcification and the lesion is not amenable to rotoblator, or a major side branch cannot be adequately protected. Patients will also be excluded if abrupt closure is likely to or would result in cardiogenic shock. Nonsignificant lesions, lesions located distally in small arteries, and lesions that supply areas of infarction will not be dilated.